

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number: K031990

B. Analyte: Troponin T

C. Type of Test: NA

D. Applicant: Roche Diagnostics Corporation.

E. Proprietary and Established Names: Roche Elecsys® PreciControl Troponin T

F. Regulatory Information:

1. Regulation section: 21 CFR §862.1660 Quality control material (assayed and unassayed).
2. Classification: Class I
3. Product Code: JJX
4. Panel: 75

G. Intended Use:

1. Intended use(s):

PreciControl Troponin T is used for quality control of the Elecsys Troponin T (Cardiac T) immunoassay on the Elecsys immunoassay systems.

2. Special condition for use statement(s): None
3. Special instrument Requirements: None

H. Device Description:

The Elecsys® PreciControl Troponin T is a lyophilized product consisting of two (2) levels, a Low Level, and High Level control manufactured using recombinant human Troponin T in human serum matrix. The analyte is spiked into the PreciControl Matrix to the correct concentration levels.

I. Substantial Equivalence Information:

1. Predicate device name(s):

Elecsys® PreciControl Cardiac

2. Predicate K number(s): K983492

3. Comparison with predicate:

Similarities between Predicate Device and Proposed Elecsys® PreciControl Troponin T

Characteristics	Predicate Device (K983492)	Proposed Product
Device Brand Name	Elecsys® PreciControl Cardiac	Elecsys® PreciControl Troponin T
Immunoassay System	Elecsys immunoassay systems	Elecsys immunoassay systems
Format	Lyophilized, based on human serum	Lyophilized, based on human serum
Handling	Reconstitute with 2 ml of distilled water and allow to stand closed for 15 minutes	Reconstitute with 2 ml of distilled water and allow to stand closed for 15 minutes
Storage Conditions	2 – 8° C	2 – 8° C
Intended Use	Used for quality control of the Elecsys CK-MB, Troponin T (Cardiac T®), and Myoglobin immunoassays using the Elecsys immunoassay system.	Used for quality control of the Elecsys Troponin T (Cardiac T®) immunoassay using the Elecsys immunoassay system.

Differences between Predicate Device and Proposed Elecsys® PreciControl Troponin T

Characteristics	Predicate Device (K983492)	Proposed Product
Analytes	Troponin T (human recombinant) CK-MB (human) Myoglobin (human)	Troponin T (human recombinant)
Concentrations of Troponin T	Low: Approx 0.15 ng/mL High: Approx 5 ng/mL	Low: Approx 0.15 ng/mL High: Approx 2.5 ng/mL
Stability	Unopened: Stable at 2-8° C until expiration date on vial Open Vial: (reconstituted): 20 - 25°C : 3 hours at 2 - 8°C : 3 days - 20°C: 3 months (freeze only once)	Unopened: Stable at 2-8° C until expiration date on vial Open Vial: (reconstituted): 20 - 25°C : 3 hours at 2 - 8°C : 3 days - 20°C: 3 months (freeze only once)

J. Standard/Guidance Document Referenced (if applicable):

FDA guidance “Points to Consider Guidance Document on Assayed and Unassayed Quality Control Materials”.

K. Test Principle: NA

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:* NA

b. *Linearity/assay reportable range:* NA

c. *Traceability (controls, calibrators, or method):*

The Elecsys PreciControl Troponin T is a lyophilized manufactured control using recombinant human Troponin T in a human serum matrix. The analyte is spiked into the matrix to the correct concentration levels.

d. *Detection limit:* NA

e. *Analytical specificity:* NA

f. *Assay cut-off:* NA

2. Comparison studies:

a. *Method comparison with predicate device:* NA

b. *Matrix comparison:* NA

3. Clinical studies:

a. *Clinical sensitivity:* NA

b. *Clinical specificity:* NA

c. *Other clinical supportive data (when a and b are not applicable):* NA

4. Clinical cut-off: NA

5. Expected values/Reference range:

Proposed Mean and Target Ranges

Approximate target values are given in the table below. Lot-specific target values may differ slightly after value assignment.

PreciControl Troponin T	Approximate Target Values
Low	0.1 ng/mL
High	2.5 ng/mL

M. Conclusion:

Based on the information provided, I recommend that the Roche Elecsys® PreciControl Troponin T is substantially equivalent to the currently marketed Elecsys® PreciControl Cardiac (K983492).